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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,348	07/03/2003	Gary Sederholm	IOI-454	7308

7590 07/05/2006

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EXAMINER

BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,348	SEDERHOLM ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 5, 2006 has been entered.

Response to Amendment

2. Applicants' amendment of claims 1, 9, and 16 in the reply filed on June 5, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 9, 13-15, and 21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Doubler et al. (US 6,692,530 B2).

Referring to Figures 1 and 4-6, Doubler et al. disclose a modular hip implant comprising a stem (11) extending from a proximal end to a distal end; a neck (46/41 and 16 collectively)

being rotationally adjustable (capable of being adjusted) about the stem; a proximal body (20) being rotationally and axially adjustable (capable of being adjusted) about the stem, and having a threaded section (threads 51); an expansible collet (40) positionable (capable of being positioned) between the stem and proximal body; and a locking member (13) having threads *adapted to engage* (emphasis added to functional language) the threaded section to lock the proximal body and collet together and to the stem. Said locking member has a ring shape in cross-section.

Response to Arguments

5. With regards to the 102(e) rejection based on Doubler et al. (US 6,692,530 B2), Applicant's arguments filed June 5, 2006 have been fully considered but they are not persuasive.
- a. Regarding claim 9, the Applicants argue: "member 20 cannot be considered as being "rotationally and axially adjustable about" member 11". The Examiner respectfully disagrees. The Applicants provided a definition of the term "about" as "in a circle around"; "on every side of". However, the term "about" is also generally defined as: "in the vicinity" (Merriam-Webster's dictionary); "in the area or vicinity; near" (www.dictionary.com). As clearly seen in Figure 1 of Doubler et al., the proximal body (member 20) is "in the area or vicinity" of stem 11.
6. Claims 9 and 13-22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by White (US 6,428,578 B2; previously cited by the Examiner).
- Referring to Figures 1, 3, 6, and 7, White discloses a modular hip prosthesis comprising (i) a stem (stem 30) extending from a proximal end to a distal end; (ii) a neck (neck 22) being

rotationally adjustable about the stem and removeably connected to the proximal end of the stem; (iii) a proximal body (body component 14) having a longitudinal bore and being both rotationally and axially adjustable about the stem, the proximal body being positioned around the stem (see Figures; see columns 4-6); (iv) a flexible/expansible sleeve (sleeve 16, comprising split collet 28) positioned between the stem and the proximal body (see Figures; see columns 4-6); and (v) a locking member (**first interpretation:** upper shoulder 38; **second interpretation:** the counter-sunk inlet disclosed at column 6, lines 33-35; **third interpretation:** referring to Figure 7, the upper sleeve 16 is the locking member, and the lower sleeve 16 is the flexible/expansible sleeve) that engages the proximal body (see Figures 1 and 7; see column 6, lines 20-37) to lock the proximal body and sleeve to the stem, wherein the neck is movable with respect to the proximal body, until being locked into position by the locking member.

7. Claims 9, 13-18, 21, and 22 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Daniels et al. (US PG PUB No. 2004/0122525). Emphasis (i.e., italics) will be added to the functional language (e.g., “adapted to engage”; “to lock”) and “capable of” (e.g., “expansible”; “movable”) language.

Referring to Figures 1-4, 7-10, and 12, Daniels et al. disclose a modular hip prosthesis (Figure 1: prosthesis 10; Figure 4: prosthesis 50), comprising:

- (i) An elongated stem (Figure 1: stem 18; Figure 4: stem 52) extending from a proximal region (Figure 1: post 28, having tapered shank 32; Figure 4: proximal stud 56) to a distal region;
- (ii) A proximal body (**first interpretation:** sleeve component 14; **second interpretation:** keyed component 94 + interdigitating component 106; **third interpretation:** sleeve component 14 +

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keyed component 94 + interdigitating component 106) having a bore (Figure 8: bore 91) and being removably *connectable* to the stem;

(iii) A neck (Figure 1: neck 12; Figure 4: neck 62) *connectable* to the proximal region of the stem;

(iv) A flexible sleeve (body taper component 90) *positionable* between the stem and proximal body; and

(v) A locking member (**first interpretation:** proximal ring 100; **second interpretation:** as shown in Figure 12, interdigitating surface 124) that engages the proximal body *to lock* the proximal body and collet together and to the stem, wherein the neck is *movable* with respect to the proximal body, until being locked into position by the locking member (see entire document).

Each of the components may be embodied as separate components (see page 4, paragraph 0053).

The components may be connected to each other by taper-fit (see page 5, paragraph 0055 and paragraph 0064).

Response to Arguments

8. With regards to the 102(e) rejection based on Daniels et al. (US PGPUB No. 2004/0122525), Applicant's arguments filed June 5, 2006 have been fully considered but they are not persuasive.

a. Regarding claim 9, the Applicants argue that “body taper component 90” is not “flexible”. The Examiner respectfully disagrees. The term “flexible” is generally defined as “capable of being bent or flexed; pliable”, “capable of being bent repeatedly without injury or damage” (see www.dictionary.com). All materials have a level/degree of flexibility, and “body taper

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component 90” construction is such that it is “capable of being bent or flexed; pliable”, “capable of being bent repeatedly without injury or damage”.

b. Regarding claim 16, the Applicants argue that “body taper component 90” is not positioned between the stem and the proximal body. Under the present/current three interpretations of “proximal body” (see 102(e) rejection), “body taper component 90” is positioned between the stem and the proximal body.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 6,428,578 B2; previously cited by the Examiner) in view of O’Neil et al. (US 5,755,800 A; previously cited by the Examiner).

White discloses the invention as claimed (see 102(e) rejection above) except for particularly disclosing his/her locking member as a cylindrical nut with external threads engaging internal threads on the proximal body. However, this is already known in the art. For example, O’Neil et al. disclose a modular joint prosthesis (Figure 5: character 80) comprising a stem (peg 22); a proximal portion (augmentation block 84) having internal threads 108; a split sleeve/collet (compression collet 88) having longitudinal slots; and a locking member (securement device 90). Securement device 90 is a cylindrical nut with external threads 120 (see

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column 7, lines 14-25). The arrangement of this interlocking system involves placing compression collet 88 between peg 22 and augmentation block 84. Once in this position, securement device 90 is engaged with augmentation block 84 by threading external threads 120 of securement device 90 onto internal threads 108 of augmentation block 84 (see column 6, line 46 to column 7, line 67), and compressing the compression collet 88 in order to create and maintain a secure engagement between the components of the modular joint prosthesis (see column 7, line 65 to column 8, line 7). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an interlocking system for a modular joint prosthesis comprising a locking member having the shape of a cylindrical nut with external threads engaging internal threads on a proximal body, as taught by O'Neil et al., with the interlocking system of the modular joint prosthesis of White, in order to create and maintain a secure engagement between the components of the modular joint prosthesis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to

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the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

June 20, 2006

A stylized, handwritten signature in black ink, consisting of a large, flowing 'J' and 'B'.A handwritten signature in black ink, appearing to read 'David H. Willse'.

David H. Willse
Primary Examiner